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(54) Title: COATED CHEWING GUM

(57) Abstract: The present invention relates to speckled, coated chewing gums, particularly those comprising an oral care active. Many oral care actives do not provide an immediately noticeable benefit and a speckle on the outer coating can provide a signal to the user of a therapeutic effect. Preferred speckling is achieved by the use of a coloured flake applied in the final stages of the coating process. A method for applying the speckled coating is also disclosed. A second aspect of this invention relates to a coated chewing gum comprising incompatible actives one active, such as a hydrolysable polyphosphate salt, is provided within the chewing gum core and a further active, incompatible with the first, such as a fluoride ion source, is provided in the coating.

#### Coated chewing gum

#### Field of the Invention

The present invention relates to coated chewing gum, that is products comprising a core of chewing gum and a crisp outer coating, typically of a sugar alcohol, and methods of making them. The invention particularly relates to coated chewing gums comprising oral care actives and in which an outer coating has distinct speckling to signal the presence of such an active.

#### Background Of The Invention

Chewing gums comprising oral care actives are known. For example, U.S. patent 5,702,687 issued to Miskewitzand discloses chewing gums comprising a polyphosphate active. Further, PCT publication WO 99/44436 discloses coated chewing gums which can comprise a variety of oral care actives.

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It is also known to provide speckled chewing gums. EP-A-192,007 discloses chewing gums in which coloured sweetener particles are distributed throughout the gum. Coated chewing gums which have a coloured outer layer are known some of which have marbling, as disclosed for example in WO 99/44436, mentioned above. However, to the applicants' knowledge, it has not previously been known to distribute a discrete speckle within the outer coating of a coated chewing gum such that it is visible on the outer coating and can therefore be used to signal the presence of an oral care active. This is

because one of the issues with developing speckled products to date has been the difficulty in applying a speckle to the outer product coating whilst maintaining a smooth finish to the final product. Further, the coated chewing gum form has not been fully utilised for delivering oral care actives which may be partially labile or otherwise incompatible with other actives used in the same product.

It is therefore an object of the present invention to provide coated chewing gums, and methods for making them, which have a discrete speckle visible on the outer coating, in particular for signalling the presence of an oral care active.

It is a further object of the present invention to provide coated chewing gums incorporating otherwise incompatible oral care actives.

It is yet a further object of the present invention to provide chewing gums comprising a hydrolytically sensitive oral care active.

These and other objects of the present invention will become readily apparent from the detailed description which follows.

All percentages and ratios used herein are by weight of the total coated chewing gum, and all measurements are made at 25°C, unless otherwise specified.

#### Summary Of The Invention

A first aspect of this invention relates to a coated chewing gum comprising a chewing gum core and a hard outer coating, having an outermost opaque layer, wherein the outer coating has a plurality of discrete flakes distributed therein, the flakes being of a different colour to the outermost surface of the outer gum coating, clearly visible on the coating of the finished product and less than 100 µm thick.

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According to a second aspect, this invention relates to a coated chewing gum comprising a chewing gum core and a hard outer coating, having an outermost opaque layer, the opaque layer having a plurality of discrete speckles distributed therein and of a different colour it; and one or more oral care actives.

In a third aspect, the invention relates to a method of preparing a speckled, coated chewing gum comprising the steps of preparing a chewing gum core; preparing a sugar or

sugar alcohol based coating solution; repeatedly applying the coating solution to the core, followed by at least partial drying after each applied coat; and thereafter applying a coating comprising a particulate speckle material, having a different colour to the dried coating solution. In this third aspect the coated and speckled gum is optionally provided with a final transparent or translucent protective coating.

In a fourth aspect, the invention relates to a coated chewing gum comprising a chewing gum core, which comprises a first oral care active; and a hard outer coating comprising a second oral care active which is incompatible with the first oral care active.

In a fifth aspect, the invention relates to a chewing gum comprising a polyphosphate salt and less than 5%, preferably less than 2%, more preferably less than 1%, by weight, total water.

## Detailed Description Of The Invention

Preferred oral care actives for use in the gums of the present invention include polymeric surface active agents including phosphorylated polymers, polyelectrolytes, and acrylate polymers. Examples include the antibacterial enhancing agents described in U.S. patents 5,032,386 and 5,840,281, both to Gaffar et al, the polymers described in U.S. patents 5,292,501; 5,213,789; 5,093,170; 5,009,882; and 4,939,284; all to Degenhardt et al. and U.S. patent 5,011,913 to Benedict et al. A preferred polymer is diphosphonate modified polyacrylic acid. Polymers with activity must have sufficient surface binding propensity to desorb pellicle proteins and remain affixed to intraoral surfaces. For tooth surfaces, polymers with end or side chain phosphate or phosphonate functions are preferred, although other polymers with mineral binding activity may prove effective depending upon adsorption affinity.

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The preferred polymeric surface active agent is a polyphosphate which, for the purpose of the present invention consists of two or more phosphate molecules arranged primarily in a linear configuration, although some cyclic derivatives may be present. Although pyrophosphates are polyphosphates, the polyphosphates preferred are those having a chain length of three or more, especially those with a chain length of around four or more phosphate molecules including tetrapolyphosphate and hexametaphosphate, among

others. Polyphosphates larger than tetrapolyphosphate usually occur as amorphous glassy materials. Preferred in this invention are the linear "glassy" polyphosphates having the formula:

# $XO(XPO_3)_nX$

wherein X is sodium, potassium, or hydrogen and n averages from about 6 to about 125. Most preferred is a particulate sodium polyphosphate with an average chain length of from about 10 to about 30, preferably from about 15 to 25, more preferably from about 21 to about 23. Such polyphosphates are manufactured by FMC Corporation and are commercially known as Sodaphos (n≈6), Hexaphos (n≈13), and Glass H (n≈21). Hexaphos and Glass H are preferred with Glass H being the most preferred polyphosphate. These polyphosphates may be used alone or in a combination thereof.

An effective amount of a polymeric surface active agent will typically be from about 0.1% to about 50%, preferably from about 1% to about 35%, more preferably from about 2% to about 25%, and most preferably from about 5% to about 15% by weight of the total chewing gum.

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Sustained release of the polymeric surface active agent from the chewing gum may be accomplished by incorporating a cationic material whose polymeric surface active agent salt is less soluble in water than the sodium, potassium or hydrogen salts. By adding such cationic material, particularly divalent cationic materials such as calcium, the release rate of the polymeric surface active agent may be tailored to a required profile. The maximum level of cationic material incorporated is one cation per monomer unit forming the polymeric surface active agent but is preferably less than 0.5 cations per monomer unit forming the polymeric surface active agent. By weight percent, the polymeric surface active agent is generally present in at least about two times the cationic material, preferably about four times the cationic material, and more preferably at least about five times the cationic material. For example, the cationic material is typically present in an amount of up to about 10%, preferably from about 0.05% to about 5%, and more preferably from about 0.1% to about 3%, by weight of the chewing gum.

The solubility of the polyphosphate is preferably at least 5g, more preferably at least 10g, even more preferably at least 15g per 100ml at 25°C. Thus the solid particulate should be "sparingly soluble", or preferably more soluble, wherein the term "sparingly soluble" is as defined in the British Pharmacopoeia, 1999, Volume 1. Whilst there is no limit on the upper solubility of the polyphosphate it is preferred that it is not "very soluble" in water.

Water employed in the preparation of commercially suitable chewing gums should preferably be of low ion content and free of organic impurities. Water will generally comprise less than about 10%, preferably less than about 5%, and more preferably less than about 3%, by weight of the gums herein. The amounts of water include the free water which is added plus that which is introduced with other materials, such as with sorbitol, silica, and solutions. In the fifth aspect of the invention which is particularly suited to the presence of polyphosphates having a chain length of four or greater, which are particularly susceptible to hydrolysis, the water content is kept to about 5% or less, preferably to about 2% or less, more preferably to about 1% or less and most preferably to about 0.5% or less.

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In similar vein, certain oral care actives, such as fluoride can be incompatible with the polyphosphates. In a fourth aspect of the invention a first oral care active is incorporated into the chewing gum core and a second, incompatible with the first, into the hard outer coating so that the two actives are kept physically separated so that they do not interact during storage of the gum. For example the first active can be a particulate sodium polyphosphate with an average chain length of from about 4 to about 30, and the second active can be a fluoride ion source, such as sodium fluoride, or vice versa. It is preferred that the polyphosphate be in the core and the fluoride ion source in the coating.

The gums of the present invention may also include other oral care actives, such as antimicrobial agents. The chewing gum composition may include an orally active metallic ion as an antimicrobial agent, particularly salts of zinc, tin and silver and copper. The preferred orally active metallic ions are zinc and tin, the latter preferably in the stannous form. Preferred zinc compounds include the acetate, lactate, citrate malate, sulphate and chloride. The orally active metallic ions are typically present in an

amount of from about 0.01% to about 10%, preferably from about 0.05% to about 5%, more preferably from about 0.1% to about 1%, by weight of the chewing gum.

Other antimicrobial agents include the water insoluble non-cationic antimicrobial agents such as halogenated diphenyl ethers, phenolic compounds including phenol and its homologs, mono and poly-alkyl and aromatic halophenols, resorcinol and its derivatives, bisphenolic compounds and halogenated salicylanilides, benzoic esters, and halogenated carbanilides. The water soluble antimicrobials include quaternary ammonium salts and bis-biquanide salts, among others. Triclosan monophosphate is an additional water soluble antimicrobial agent. Dodecyl trimethyl ammonium bromide, tetradecylpyridinium chloride, domiphen bromide, N-tetradecyl-4-ethyl pyridinium chloride, dodecyl dimethyl (2-phenoxyethyl) ammonium bromide, benzyl dimethylstearyl ammonium chloride, cetyl pyridinium chloride, cetyl pyridinium saccharinate, quaternized 5-amino-1,3-bis(2-ethyl-hexyl)-5-methyl hexa hydropyrimidine, benzalkonium chloride, benzethonium chloride and methyl benzethonium chloride are exemplary of typical quaternary ammonium antibacterial agents.

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Also useful are enzymes, including endoglycosidase, papain, dextranase, mutanase, and mixtures thereof. Such agents are disclosed in U.S. Patent 2,946,725, Jul. 26, 1960, to Norris et al. and in U.S. Patent 4,051,234, September. 27, 1977 to Gieske et al., incorporated herein by reference.

An abrasive polishing material may be included in the chewing gums of the present invention. The abrasive polishing material contemplated for use in the compositions of the present invention can be any material which does not excessively abrade dentine. The abrasive polishing material should be formulated in the chewing gum composition so that it does not compromise the stability of any ingredients. Typical abrasive polishing materials include silica gels and precipitates; aluminas; water insoluble phosphates and mixtures thereof. Specific examples include dicalcium orthophosphate dihydrate, calcium pyrophosphate, tricalcium phosphate, calcium polymetaphosphate, insoluble sodium polymetaphosphate, hydrated alumina, beta calcium pyrophosphate, calcium carbonate, and resinous abrasive materials such as particulate condensation products of urea and

formaldehyde. Mixtures of abrasives may also be used. The abrasive in the chewing gum compositions is generally from about 1% to about 70% and preferably from about 5% to about 50%, by weight of the chewing gum composition.

Apart from the preferred oral care actives, the chewing gum core of the present invention is substantially conventional and includes elastomer gum bases, solvents, fats, resins, waxes, plasticisers, emulsifiers, softeners, bulking agents, sweeteners, flavorants and other materials as commonly employed in the art. Such materials are well known and are readily chosen by one skilled in the art based on the physical and aesthetic properties desired for the chewing gum compositions being prepared. Any type of sweetener can be used in compositions of the present invention including bulk sweeteners and high intensity sweeteners. In general, the amount of sweetener used will vary depending on the sweetener and the overall desired aesthetics but levels used should be high enough such that the desired level of sweetness is achieved independent from the flavour level achieved from the flavouring agents. The chewing gums are, however, preferably sugar free. The term "sugar free" is commonly used with respect to chewing gum and thus would be understood by one skilled in the art in the field of confectionery. Suitable examples of bulk sweeteners for use in compositions of the present invention include monosaccharides, disaccharides, and polysaccharides. Preferred bulk sweetening agents are sugar alcohols such as sorbitol, xylitol, mannitol, maltitol, isomalt, hydrogenated starch hydrolisate, inulin, and other non-carigenic edible polyols such as glycerin and erythritol and mixtures thereof. Suitable high intensity sweeteners include: dipeptide based sweeteners such as L-aspartyl-L-phenylalanine methyl ester (Aspartame) and equivalents (described in U.S. Pat. No. 3,492,131), L-α-aspartyl-N-(2,2,4,4-tetramethyl-3thietanyl)-D-alaninamide hydrate (Alitame) and the like; saccharin and its soluble salts eg sodium or calcium saccharin salts; cyclamate salts for example acesulfame-K and the like; chlorinated derivatives of sucrose such as chlorodeoxysucrose and the like; and protein based sweeteners, such as Thaumatin (talin).

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The gums may also include buffering agents to adjust the pH of the chewing gum and may help to stabilise the polymeric surface active agent. An alkali metal bicarbonate salt, surfactants, whitening agents such as peroxide or percarbonate, colouring agents, xylitol,

thickening materials, binders, humectants, absorbents such as activated carbon, silica absorbents, cyclodextrins, and zeolites and combinations thereof, may also be included in the chewing gums.

The chewing gum composition may be in the form of a chiclet or other form that contains a outer coating or shell around the central portion or gum base of the chewing gum. The outer coating is preferably hard or crunchy. Typically, the outer coating will essentially consist of sorbitol, maltitol, xylitol, isomalt, and other crystallisable polyols. Furthermore the coating will typically consist of several opaque layers, such that the gum core is not visible through the coating itself, which can optionally be covered with a further one or more transparent layers for aesthetic, textural and protective purposes. The outer coating may also contain small amounts of water and gum arabic. A polyol coating can be further coated with wax. The coating is applied in a conventional manner by successive applications of a coating solution, with drying in between each coat, as described in WO99/44436. As the coating dries it usually becomes opaque and is usually white, though other colorants may be added.

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In the first to third aspects of the invention the outer opaque layer has a speckle distributed therein. As referred to herein a speckle is understood to be a discrete particle visible on the outer coating of the gum wherein the particle is of sufficiently different colour to the opaque coating that it is easily visible and is not blurred with the coating material. It can be formed from any food grade material and it is highly preferred that the material is water insoluble. It is also highly preferred that the speckles are in the form of an essentially planar discrete particulate flake with a thickness of less than 100 µm, preferably less than 50 µm, and a width and length generally in the range of from 0.1 to 7mm, preferably 0.2 to 2mm. However, other types of coloured speckles, for example those with a less planar structure such as those formed by encapsulating coloured wax shapes, should also be considered as a speckle within the scope of the second and third aspects of the present invention provided that in all cases they form a discrete speckle on the final product which is easily visible against the background opaque coating. The speckle material can either be located on the outer surface of the opaque gum coating or it

can be dispersed within the opaque gum coating providing that a sufficient amount of the speckle, on the final product, is clearly visible as a discrete non blurred, coloured particle. It is highly preferred that the speckle is located solely on the outer surface of the opaque coating. Thin speckle flakes such as those described above are especially useful since, as a result of their essentially planar structure, they lie flat on the gum outer coating. Thus, if applied to the outer surface of the opaque coating, a minimal number of further transparent coating layers are required to achieve a smooth and protected finish to the gum. An exemplary speckle material is "Insoluble Edible Glitter" available from Watson Food Co., West Haven, CT., USA. This material is highly preferred due to its thin, planar, flake structure, insoluble nature and also due to its exceptional colour properties which are that it is bright, shiny, translucent and iridescent. Used at a low level, preferably less than 0.1% by weight of the coating, more preferably less than 0.05% by weight of the coating, these insoluble flakes adhere well to the outer opaque coating and lie flat on the surface thus providing a discrete speckle which does not become blurred. Suitably this results in less than 5% of the outer layer surface being covered with speckle. It has been found that this speckling, without interfering with the coating texture, provides an appropriate consumer signal of the presence of an active, whose effect may be a longterm therapeutic one and not otherwise immediately noticeable.

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The speckles can be added to the coating of the gum by any means known to those skilled in the art. For example the speckles can be dispersed in the opaque gum coating material and then applied to the gum as a coating dispersion. Alternatively the speckles can be dispersed in the transparent gum coating and applied as a dispersion on top of the opaque layer. Alternatively the speckle can be sprayed, wet or dry, onto the gum coating, either onto the outermost opaque layer, or the outermost transparent layer. Optionally, once the speckle has been applied, the gum can be provided with a transparent or translucent protective coating, such as a wax or sorbitol solution, to prevent the speckle being rubbed off. For the flaked speckle it is preferred that the speckle is dry sprayed onto the outermost opaque layer of the coated gum before that layer is dry. This dry spraying gives the advantage that the speckle is applied flat against the gum coating and that few

additional coating layers are required to produce the desired smooth texture to the finished product.

## Examples & Method of Manufacturing

The following example demonstrates an embodiment within the scope of the present invention. This example is given solely for the purpose of illustration and is not to be construed as a limitation of the present invention as many variations thereof are possible without departing from the scope.

## 10 Example I

Ingredient	Core	Coating	Complete	
	Formulation	Formulation	formulation	
	% <sup>W</sup> / <sub>W</sub>	% <sup>W</sup> /w	% <sup>W</sup> / <sub>W</sub>	
	lg per piece	0.35g per piece	1.35g per piece	
Sorbitol	49.35	-	36.55	
Gum base <sup>1</sup>	25.0	-	18.52	
Sodium polyphosphate, n=212	10.0	•	7.41	
Sodium fluoride	-	0.08	0.02	
Xylitol	•	-	-	
Hydrogenated Starch Hydrolisate	5.0		3.70	
Mannitol	2.0		1.48	
Glycerine	5.0	-	3.70	
Titanium dioxide		2.0	0.52	
Flavour	2.0	2.0	2.00	
Additional spray-dried flavour	1.5	-	1.11	
Sucralose	0.05	0.03	0.05	
Potassium Acesulfame	0.10	0.10	0.10	
Sorbitol <sup>3</sup>	-	95.25	24.70	

Polysorbate 60	-	0.30	0.08
Insoluble edible glitter <sup>4</sup>	-	0.04	0.01
(Brilliant Blue)			
Wax <sup>5</sup>		0.20	0.05
TOTAL	100.00	100.00	100.00

# Example II

Ingredient	Core	Coating	Complete
	Formulation	Formulation	formulation
	% <sup>W</sup> /w	% <sup>W</sup> /w	% <sup>W</sup> / <sub>W</sub>
	lg per piece	0.35g per piece	1.35g per piece
Sorbitol		-	
Gum base <sup>1</sup>	25.0	_	18.52
Sodium polyphosphate, n=212	10.0		7.41
Sodium fluoride		-	-
Xylitol	53.35	-	39.52
Hydrogenated Starch Hydrolisate			-
Mannitol	_	•	-
Glycerine	8.0	-	5.93
Titanium dioxide	<b>.</b>	2.0	0.52
Flavour	2.0	2.0	2.00
Additional spray-dried flavour	1.5		1.11
Sucralose	0.05	0.03	0.05
Potassium Acesulfame	0.10	0.10	0.10
Sorbitol <sup>3</sup>	-	95.33	24.70
Polysorbate 60	-	0.30	0.08
Insoluble edible glitter <sup>4</sup>	-	0.04	0.01
(Brilliant Blue)			

Wax⁵	•	0.20	0.05
TOTAL	100.00	100.00	100.00

# Example III

Ingredient	Core	Coating	Complete
	Formulation	Formulation	formulation
	% <sup>W</sup> / <sub>W</sub>	% <sup>W</sup> / <sub>W</sub>	% <sup>W</sup> / <sub>W</sub>
	1g per piece	0.35g per piece	1.35g per piece
Sorbitol	46.35	-	34.33
Gum base <sup>1</sup>	35.0	-	25.93
Sodium polyphosphate, n=212	3.0		2.22
Sodium fluoride	**	0.08	0.02
Xylitol		-	-
Hydrogenated Starch Hydrolisate	5.0	-	3.70
Mannitol	2.0	_	1.48
Glycerine	5.0	-	3.70
Titanium dioxide		2.0	0.52
Flavour	2.0	2.0	2.00
Additional spray-dried flavour	1.5		1.11
Sucralose	0.05	0.03	0.05
Potassium Acesulfame	0.10	0.10	0.10
Sorbitol <sup>3</sup>	=	95.25	24.70
Polysorbate 60	-	0.30	0.08
Insoluble edible glitter <sup>4</sup>	•	0.04	0.01
(Brilliant Blue)			
Wax <sup>5</sup>		0.20	0.05
TOTAL	100.00	100.00	100.00

# <u>Example IV</u>

Ingredient	Core	Coating	Complete
	Formulation	Formulation	formulation
	% <sup>W</sup> /W	% <sup>W</sup> / <sub>W</sub>	% <sup>W</sup> / <sub>W</sub>
	1g per piece	0.35g per piece	1.35g per piece
Sorbitol	12.35	-	9.15
Gum base <sup>1</sup>	35.0	•	25.93
Penta sodium triphosphate, n=36	7.0		5.19
Sodium fluoride	-	-	-
Xylitol	30.0	-	22.22
Hydrogenated Starch Hydrolisate	5.0	-	3.70
Mannitol	2.0	-	1.48
Glycerine	5.0	-	3.70
Titanium dioxide	-	· 2.0	0.52
Flavour	2.0	2.0	2.00
Additional spray-dried flavour	1.5	-	1.11
Sucralose	0.05	0.03	0.05
Potassium Acesulfame	0.10	0.10	0.10
Sorbitol <sup>3</sup>	-	95.33	24.70
Polysorbate 60	-	0.30	0.08
Insoluble edible glitter <sup>4</sup>	-	0.04	0.01
(Brilliant Blue)			,
Wax <sup>5</sup>		0.20	0.05
TOTAL	100.00	100.00	100.00

<sup>1</sup> Comprises several ingredients, including pre-supplied gum bases from suppliers such as L. A. Dreyfus Company, 3775 Park Avenue, Edison, N. Jersey, US; Cafosa Gum, Calabria 267, 08029, Barcelona, Spain etc

Supplied by F. M. C. Corporation, Phosphorus Chemical Division, 1735 Market Street, Philadelphia, Pennsylvania, US

- <sup>3</sup> Level of Sorbitol refers to absolute level after drying; Sorbitol is added as a 70% aqueous solution
- <sup>4</sup> Watson Foods Company Incorporated, 301 Heffernan Drive, West Haven, Connecticut, USA
- <sup>5</sup> Level of wax refers to absolute level after drying wax is added as a 28% ethanolic solution; wax used comprises several ingredients such as that supplied by Kaul GmBH, Elmshorn, Germany
- 5 Supplied by Albright and Wilson, PO Box 26229, Richmond, Virginia, USA

## **Making Instructions**

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Core Formulation: Soften gum base with gentle heating and add mannitol, spray-dried flavour, glycerine, 50% of xylitol, hydrogenated starch hydrolisate, 50% of sorbitol and mix thoroughly. Add second 50% of xylitol, sodium polyphosphate and aspartame, remainder of flavour and mix further. Form bulk chewing gum mass into discrete pieces of desired shape and size using rolling and scoring equipment.

<u>Coating Solution</u>: Add titanium dioxide and Polysorbate 60 to 70% aqueous sorbitol solution and mix. Add flavour followed by Sucralose and Potassium Acesulfame and mix further.

Coating of Core Formulation: Place gum pieces into a coating pan and apply coating solution, partially dry. Repeat coating step until desired coating thickness or weight is achieved. Apply clear 70% aqueous sorbitol solution and, whilst wet, dry spray speckles onto product surface, dry. Apply second coat of clear 70% sorbitol solution followed by wax coating and allow product to fully dry.

#### Claims

1. A coated chewing gum comprising:

- a) a chewing gum core;
- b) a hard outer coating having an outermost surface;

wherein the outer coating has a plurality of discrete flakes distributed therein, the flakes being of a different colour to the outermost surface of the outer gum coating, clearly visible on the coating of the finished product and less than 100 µm thick.

- 2. A chewing gum according to Claim 1 wherein the discrete flakes distributed on the outermost opaque layer are water insoluble.
- 3. The chewing gum according to any of Claims 1 or 2 wherein the gum further comprises one or more oral care actives selected from polyphosphates, pyrophosphates, fluoride and orally active di- or polyvalent metal ions.
- 4. The chewing gum according to Claim 3 wherein the one or more oral care actives comprise a polyphosphate.
- 5. A coated chewing gum comprising:
  - a) a chewing gum core;
  - b) a hard outer coating, having an outermost opaque layer, wherein the opaque layer has a plurality of discrete speckles distributed therein and of a different colour it; and
  - c) one or more oral care actives.
- 6. A chewing gum according to Claim 5 wherein the discrete speckles distributed within the outermost opaque layer are water insoluble.
- A chewing gum according to Claim 6 wherein the discrete speckles distributed within the outermost layer are flakes with a thickness of less than 100μm.
- 8. A method of preparing a speckled, coated chewing gum comprising the steps of:
  - a) preparing a chewing gum core;

- b) preparing a sugar or sugar alcohol based coating solution;
- repeatedly applying the coating solution to the core, followed by at least partial drying after each applied coat to form a coating having an outermost opaque layer;
- d) thereafter applying a coating comprising a particulate speckle material, having a different colour to the coating solution; and
- e) optionally, providing a transparent or translucent protective coating.
- 9. A method according to Claim 8 wherein the speckle is a flake with a thickness of less than 100μm.
- 10. A method according to any of Claims 8 or 9 wherein the speckle coating is sprayed as a dry material onto the outermost opaque layer of the coating before that layer is completely dry.
- 11. A coated chewing gum comprising;
  - a) a chewing gum core comprising a first oral care active;
  - b) a hard outer coating comprising a second oral care active which is incompatible with the first.
- 12. A chewing gum according to Claim 11 wherein the first or the second oral care actives is a polyphosphate and the other of the first or the second oral care actives is a fluoride ion source.
- 13. A chewing gum comprising a polyphosphate salt and less than 5%, preferably less than 2%, more preferably less than 1%, by weight, total water.
- 14. A chewing gum according to Claim 13 wherein the polyphosphate salt has a chain length of 4 or greater.

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A CLASSIFICATION OF SUBJECT MATTER IPC 7 A23G3/00 A23G3/30

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) I PC  $\,\,7\,\,\,\,\,\,$  A23G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, FSTA

O. DOCOMII	ENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of t	he relevant passages	Relevant to claim No.
X	EP 0 516 310 A (WRIGLEY W M J 2 December 1992 (1992-12-02) column 8, line 12-19; claims : examples 1,5,6 column 1, line 1-16 column 3, line 19-32	1,2,4,7,9,15;	1,2,8,9
Α	column 5, line 55 -column 6,	line 45	3-7,10
X	WO 97 12607 A (CHURCH & DWIGHT 10 April 1997 (1997-04-10) cited in the application	CO INC)	1-7
A	claims 1,5,8,11,13,18,22,30,3 examples 2-4 page 12, line 24-28 page 13, line 22 -page 14, lin page 16, line 18-27 page 18, line 15-23		8-10
X Furth	er documents are listed in the continuation of box C.	X Patent family members are liste	ed in annex.
A" documer conside E" earlier do filing de L" documer which is citation O" documer other m documer later tha	It which may throw doubts on priority claim(e) or so cited to establish the publication date of another or other special reason (as specified) at referring to an oral disclosure, use, exhibition or eans at published prior to the international filling date but an the priority date claimed	"T" later document published after the Ir or priority date and not in conflict wi cited to understand the principle or invention "X" document of particular relevance; the cannot be considered novel or cannot involve an inventive step when the "Y" document of particular relevance; the cannot be considered to involve an document is combined with one or ments, such combination being obv in the art.  "&" document member of the same pater	th the application but theory underlying the e claimed invention not be considered to document is taken alone a claimed invention invention step when the more other such docutions to a person skilled
ate of the a	ctual completion of the international search	Date of mailing of the International s	earch report
11	. July 2001	08. 10. 2	001
ame and ma	ailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo пl,	Authorized officer Tallgren, A	

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egory °	Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.		
g,	appropriate, or an elevant passages		nerevant to claim No.		
	WO 97 22264 A (CHURCH & DWIGHT CO INC)	<del></del>	1-7		
	WO 97 22264 A (CHURCH & DWIGHT CO INC) 26 June 1997 (1997-06-26)		1 1-/		
	page 18, paragraphs 10-19; claims 1.15;		8-10		
	examples 2,4				
	DE 37 32 677 A (LINGNER & FISCHER GMBH)		1,2,5-7		
	6 April 1989 (1989-04-06)		1,2,5-/		
	column 4, line 14-60; claims				
	1,9,11,12,15,18; figures 1-7 column 7, line 57 -column 8, line 15,33-35				
	US 4 127 677 A (FRONCZKOWSKI PAUL R ET AL)		1-10		
	28 November 1978 (1978-11-28) claims 1,7,8; examples 1-12				
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national application No. PCT/US 00/27138

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
Claims Nos.:     because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
see additional sheet
see dan Fronti Sheet
As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. X No required additional search fees were timely pald by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-10
Remark on Protest  The additional search fees were accompanied by the applicant's protest.
No protest accompanied the payment of additional search fees.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-10

A coated chewing gum comprising a chewing gum core and a hard outer coating having an outermost surface. On the outer coating there are a plurality of coloured discrete flakes within a thickness less than  $100~\rm um$ .

2. Claims: 11-12

A coated chewing gum comprising a chewing core with a first oral active and a hard outer coating comprising a second oral care active, which is incompatible with the first.

3. Claims: 13-14

a chewing gum comprising a polyphosphate salt and less than 5 %, preferably less than 2 %, more preferably less than 1 %, by weight, total water.

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Patent document cited in search report		Publication date		Patent family member(s)	Publication date
EP 0516310	A	02-12-1992	US AT AU CA DE DE DK EP FI MX	5171589 A 123922 T 646616 B2 1729792 A 2068797 A1 69203040 D1 69203040 T2 516310 T3 0516310 A2 922181 A 9202592 A1	15-12-1992 15-07-1995 24-02-1994 03-12-1992 01-12-1992 27-07-1995 01-02-1996 21-08-1995 02-12-1992 01-12-1992 01-04-1993
WO 9712607	A	10-04-1997	US AU WO	5702687 A 6969896 A 9712607 A1	30-12-1997 28-04-1997 10-04-1997
WO 9722264	A	26-06-1997	US AU WO	5629035 A 7473296 A 9722264 A1	13-05-1997 14-07-1997 26-06-1997
DE 3732677	Α	06-04-1989	DE	3732677 A1	06-04-1989
US 4127677	Α	28-11-1978	NONE	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	